

REMARKS

Claims 1-14 are pending in the above-identified application and stand ready for further action on the merits.

Enclosed 37 CFR § 1.132 Declaration

Enclosed with the present response is a 37 CFR § 1.132 Declaration of Mr. Yasushi Ochiai, one of the present co-inventors. The accompanying Declaration has been prepared and signed by Mr. Ochiai to evidence that patentable differences and distinctions exist between the present invention as claimed and the disclosure of Pierre et al. (US 5,300,318). In this respect, the Declaration is pertinent to the Examiner's outstanding rejection under 35 USC § 103(a) set forth below, and a full review thereof is thus respectfully requested. In particular, the Examiner is respectfully requested to consider differences shown by Figures 26-27 versus Figures 23-25 and to also consider Figures 29-30 versus Figure 28. The Examiner is also requested to fully consider the conclusion set forth at page 14 of Mr. Ochiai's Declaration, as well as the Description of Figures occurring at pages 11-13 of the Declaration.

Although Applicants have requested that the Examiner pay special attention to certain parts of Mr. Ochiai's accompanying Declaration, the Examiner is also requested to fully and completely

review the Declaration, in as much as all Comparative Testing set forth therein is supportive of the patentability of the present claims 1-14.

Claim Rejections Under 35 USC § 103

Claims 1-14 are rejected under 35 USC § 103(a) as being unpatentable over Pierre et al. (US 5,300,318). Reconsideration and withdrawal of this rejection is respectfully requested based upon the following remarks and the submission herewith of the accompanying Declaration of Mr. Yasushi Ochiai under 37 CFR § 1.132.

The present invention relates to a method of manufacturing drug granules, and more particularly provides a pharmaceutical preparation containing a water-soluble drug as an active ingredient at a high density, which shows superior stability in a uniform content.

In the method of manufacturing a drug granule as instantly claimed, a granulation step of spraying a solution of a water-soluble drug on a crystal of said water soluble drug takes place. (See claim 1.) In other aspects of the present invention, the solution of the water-soluble drug is sprayed substantially without using a binder or in the absence of a binder, and wherein the drug granule has a granule strength of 650-2500 gf/mm². (See claim 2.)

An important aspect of the present invention relates to the granular strength of the granules, since it allows for the granules to be "tableted" or subjected to a "tableting" step, without breaking of the granules. This aspect of the present invention is also significant when the claimed inventive methods also contain a step of "coating said drug granule with a release control film coating agent." (See claims 7-11 and 14.)

The above aspects of the present invention are nowhere taught, disclosed or otherwise rendered obvious by the disclosure of Pierre et al. (US '318). For example, Pierre et al. (US '318) does not provide any suggestion regarding granular strength and/or tableting of coated granules.

In contrast to the teachings of Pierre et al. (US '318), the present invention provides granules having sufficient granule strength to be capable of maintaining a coating film during tableting processes, and thereby also allow for the manufacture of tablets from the coated granules having desirable and suitable dissolution characteristics. On this point, the Examiner is invited to review Mr. Ochiai's Declaration, particularly Figures 29-30 versus Figure 28, and also the discussion at page 14 thereof.

As also evidenced in the accompanying Declaration of Mr. Ochiai, test results provided show that the granular strength of the present inventive granules is quite distinct and different from

that of Pierre et al. (US '318). The results show that a difference exists with regard to the inner structure of the granules between the present invention and Pierre et al. The maintaining of a coating film and granule structure after tableting reflects the difference of granular strength. Please see Figures 26-27 versus Figures 23-25 in the accompanying Declaration.

As indicated in the accompanying Declaration at page 14, Mr. Yasushi Ochiai clearly believes that one of ordinary skill in the art, even upon considering the disclosure of Pierre et al. (US '318) would in no way be motivated to arrive at the instant invention as claimed, or otherwise be lead to arrive at the instant invention and the unexpected and advantageous properties that are possessed thereby. This of course is one of the touchstones for determining obviousness or non-obviousness.

Accordingly, based upon a consideration of the above remarks and the comparative test results in Mr. Ochiai's accompanying Declaration and the conclusions made therein at page 14 based on such test results, it follows that the outstanding rejection under 35 USC § 103(a) of claims 1-14 over Pierre et al. (US '318) must now be withdrawn.

CONCLUSION

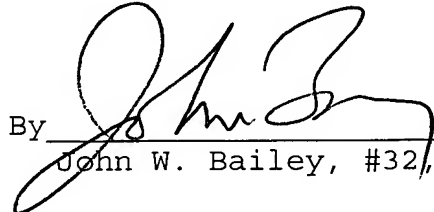
Based upon the remarks presented herein, as well as the comparative testing results and conclusions based thereon set forth in Mr. Ochiai's accompanying 37 CFR § 1.132 Declaration, the Examiner is respectfully requested to issue a Notice of Allowance clearly indicating that each of the pending claims 1-14 are allowable at present.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact John W. Bailey (Reg. No. 32,881) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By  _____
John W. Bailey, #32,881

JWB/enm
4367-0101P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachment(s): 37 CFR § 1.132 Declaration of Mr. Yasushi Ochiai